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HIGH PRODUCTION VOLUME (HPV)
CHEMICAL CHALLENGE PROGRAM

FINAL SUBMISSION

for

**ROSINS
AND
ROSIN SALTS**

CAS No. 8050-09-7
CAS No. 65997-06-0
CAS No. 68425-08-1
CAS No. 61790-50-9
CAS No. 61790-51-0
CAS No. 68783-82-4

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Final Submission for Rosins and Rosin Salts

Summary

As part of the High Production Volume (HPV) Program, the Pine Chemicals Association, Inc. (PCA) has sponsored six HPV chemicals. This final submission addresses the following six chemicals, known collectively as Rosins and Rosin Salts:

CAS 8050-09-7, Rosin
CAS 65997-06-0, Rosin, hydrogenated
CAS 68425-08-1, Rosin, distillation overheads
CAS 68783-82-4, Rosin, low boiling fraction
CAS 61790-50-9, Rosin, potassium salt
CAS 61790-51-0, Rosin, sodium salt

This summary encompasses data previously described in the Test Plan for these substances as well as newly acquired data. The totality of the data shows that these chemicals are all non-toxic.

All of the members of this group of substances are closely related to rosin, which is a naturally occurring substance found in trees, predominantly pine trees. Rosin is composed primarily of resin acids, a class of tricyclic carboxylic acids, but also contains minor amounts of dimerized rosin and unsaponifiable matter. Because of the complex nature of their composition, rosin and the rest of the compounds in this group are considered to be "Class 2" substances.

Rosin is an important commercial material and has been used for centuries. Industrially, there are three different types of rosin: gum, wood and tall oil rosin, with the name indicating the way in which the rosin is extracted from the tree. In the United States, tall oil rosin is by far the most commercially important variety. Rosin (CAS# 8050-09-7) also now includes CAS# 8052-10-6, rosin, tall oil, which was used in the 1990 IUR reporting on which the HPV program was based, pursuant to EPA's letter to PCA of March 13, 1992.

Rosin is used primarily as the raw material for the production of rosin derivatives, which go into the production of a wide variety of industrial products. For example, the largest use of rosin is in the production of derivatives for printing inks, adhesives, and coatings. Rosin salts are widely used in paper sizing. Other members of the group are used to produce soaps and detergents or to impart enhanced stability to specialty rosin-based adhesives.

Where applicable, PCA conducted physical/chemical property and environmental fate testing on five of the substances in the group. (Two of the substances, rosin distillation overheads and rosin low boiling fraction, are identical so that physical/chemical testing was only conducted on one of them.)

With respect to toxicological testing, available data showed that rosin is non-toxic in acute, repeat dose, reproductive and genotoxicity studies. For the other SIDS endpoints including developmental and ecotoxicity, PCA tested a representative substance from the category. PCA elected to treat this group of chemicals as a category for purposes of the HPV program.

Rosin (CAS# 8050-09-7) was selected as the representative substance in this category for testing for the additional SIDS endpoints. Rosin represents by far the greatest production volume, with almost four times more rosin manufactured than all other substances in this category combined. In addition, rosin is the raw material from which all the other category members are derived. Consequently, test results obtained on rosin will be most representative of the category.

The totality of the SIDS data for the substances in this category is briefly summarized below and in Tables 1-3. As shown in these summaries, rosin and rosin salts are all non-toxic in both mammalian and aquatic test systems. These data are described and discussed in the main document. Detailed Robust Summaries of all relevant data are appended to this document.

Physical/Chemical Properties

Physical and chemical properties were determined where appropriate; however, many of these endpoints are either inappropriate or cannot be measured for these compounds:

- Melting or boiling points were not determined because these substances will either will not give a sharp melting point when heated or will decompose before they melt or boil.
- Under ambient conditions, the vapor pressure of these chemicals is essentially zero and experimental measurement is not possible.
- Water solubility and partition coefficients are summarized in Table 1. It should be noted that although all of the non-salt substances in this category are essentially insoluble in water, considerable effort was undertaken to accurately determine water solubility.
- With respect to the partition coefficient (K_{ow}), the approved method (OECD 117) yields a range of values rather than a single value representative of the mixture. The range of values reflects the partition coefficients of the individual constituents of these complex mixtures.

The details on these test results are provided in the Robust Summaries.

Table 1. Summary of Physical/Chemical and Environmental Fate Data*

Chemical Name	Required SIDS Endpoints		
	Partition Coefficient	Water Solubility (mg/l)	Percent Biodegradation At 28 Days
Rosin	1.9 – 7.7	0.9	32
Rosin, hydrogenated	2.5 – 7.6	1.18	0.95
Rosin, distillation overheads	2.5 – 7.8	19.85	30
Rosin, low boiling fraction ^a	2.5 – 7.8	19.85	30
Rosin, potassium salt	3.0 – 7.0	Mutually miscible	89.5
Rosin, sodium salt	3.5 – 6.6	Mutually miscible	80

*No testing was conducted for melting point, boiling point, vapor pressure, hydrolysis, photodegradation, and transport and distribution between environmental compartments as explained in main document.

a: Rosin, distillation overheads and rosin, low boiling fraction are identical as explained in main document.

Environmental Fate

The SIDS environmental fate endpoints were determined where appropriate; however, many of these endpoints are either inapplicable or cannot be measured for these compounds.

- Photodegradation was not relevant, since the vapor pressure of these compounds is essentially zero and they could not enter the atmosphere.
- Hydrolysis in water was not determined for any of the compounds in this category because all have low water solubility and also lack a functional group that would be susceptible to hydrolysis.
- Transport and distribution between environmental compartments (i.e., fugacity) was not determined due to the inability to provide usable inputs to the required model.
- Biodegradation data are summarized in Table 1 and show that, with the exception of rosin, hydrogenated, these substances are substantially biodegradable in the environment.

The details on these test results are provided in the Robust Summaries.

Ecotoxicity

Rosin was tested for acute toxicity to fish, daphnia and algae at the maximum measured water solubility. These data are summarized in Table 2 and show that none of the compounds in this category are toxic to algae, daphnia or fish. The details of these test results are provided in the Robust Summaries.

Table 2. Summary of Ecotoxicity Data

Chemical Name	Required SIDS Endpoint		
	Acute Fish 96 hr NOEL _r	Acute Daphnia 48 hr NOEL _r	Acute Algae 72 hr NOEL _r
Rosin	1000 mg/l	750 mg/l	1000 mg/l
Rosin, hydrogenated	C	C	C
Rosin, distillation overheads	C	C	C
Rosin, low boiling fraction	C	C	C
Rosin, potassium salt	C	C	C
Rosin, sodium salt	C	C	C

C = Indicates category read-down from available data

NOEL_r = no observed effect loading rate

Mammalian Toxicity

For the SIDS human health endpoints, there were adequate data on acute toxicity, repeat dose toxicity, and reproductive effects for both rosin and hydrogenated rosin demonstrating that these compounds are non-toxic. The availability of two-year feeding studies on rosin and hydrogenated rosin showing a lack of carcinogenicity obviated the need for *in vitro* genotoxicity testing. A developmental toxicity study on rosin demonstrated a NOEL of 1000 ppm (105 mg/kg/day) for adults and a NOEL of 3000 ppm (300 mg/kg/day) for reproductive and developmental effects. The mammalian toxicity data are summarized in Table 3 and demonstrate that rosin is non-toxic. Based on the category approach, it can be inferred that results for the test substance also represent other members of the category. The details of these test results are provided in the Robust Summaries.

Table 3. Summary of Mammalian Toxicity Data

Chemical Name	Required SIDS Endpoints				
	Acute Oral	Repeat Dose	In vitro genotox (Mutation)	In vitro genotox (Chromosomal aberration)	Repro/ Develop
Rosin	LD ₅₀ > 5000 mg/kg	NOEL 105 -200 mg/kg/d	No tumors in 2 yr. cancer bioassay ^a	No tumors in 2 yr. cancer bioassay ^a	NOEL 275 mg/kg/d
Rosin, hydrogenated	LD ₅₀ > 5000 mg/kg	C	C	C	C
Rosin, distillation overheads	C	C	C	C	C
Rosin, low boiling fraction	C	C	C	C	C
Rosin, potassium salt	C	C	C	C	C
Rosin, sodium salt	C	C	C	C	C

C = Indicates category read-down from available data.

a = see main document for explanation.

Overall Hazard Evaluation and Potential Exposure

For potential human health effects, the totality of the SIDS data demonstrates that rosin is non-toxic. Accordingly, based on the category approach, it can be inferred that all of the substances in this group are also non-toxic.

Rosin has no acute oral toxicity (i.e., $LD_{50} > 5,000$ mg/kg), and repeat dose toxicity data demonstrate a no observed effect level (NOEL) of approximately 105 - 200 mg/kg/day and a NOEL of approximately 275 mg/kg/day for reproductive/developmental effects. The lack of acute oral toxicity (i.e., $LD_{50} > 5,000$ mg/kg) for rosin, hydrogenated, is confirmatory of the lack of acute toxicity of the substances in this category. The lack of carcinogenic effects in two-year feeding studies for rosin and rosin, hydrogenated suggests that neither substance is genotoxic.

Consequently, no adverse health consequences would be associated with any exposures to any of the rosins or rosin salts. For potential ecotoxicological effects, the data on rosin demonstrate that all of the substances in this category are non-toxic to aquatic organisms with the $NOEL_r$ for fish and algae of 1000 mg/l and the $NOEL_r$ for daphnia of 750 mg/l.

With respect to potential exposure to the substances in this category, all are consumed almost entirely in the production of other chemical intermediates. Rosin is reacted in a variety of ways to form salts, adducts, esters, dimers and other reaction products which find application in the production of printing inks, adhesives (primarily hot melt packaging adhesives), paper size, and coatings. These uses would be considered non-dispersive in that the rosin derived chemical is reacted or otherwise contained within the article in which it is being used. It is estimated that greater than 80% of the various rosin derivatives are used in the type of applications described above. As such inhalation exposure or volatilization to air is minimal due to a lack of vapor pressure for these substances. Exposure in the listed applications is generally limited to dermal contact during the processing, finishing and shipping of the products of which they become a part. Approximately 3% of rosin is reacted to form specific rosin esters which are marketed to the chewing gum industry. These derivatives are cleared for direct food contact by the US FDA

The Pine Chemicals Association, Inc. HPV Task Force includes the following companies:

Akzo Nobel Resins
Akzo Nobel - Eka Chemicals Incorporated
Arizona Chemical Company
Asphalt Emulsion Manufacturers Association
Boise Cascade Corporation
Cognis Corporation
Crompton Corporation
Eastman Chemical Co. (including the former Hercules Inc. Resins Division)
Georgia-Pacific Resins Inc.
Hercules Inc.
ICI Americas (including the former Uniqema)
Inland Paperboard & Packaging, Inc.
International Paper Co. (including the former Champion International Corporation)
Koch Materials Co.
McConaughay Technologies, Inc.
Mead Westvaco (includes the former Westvaco)
Packaging Corporation of America
Plasmine Technology, Inc.
Raisio Chemicals
Rayonier
Riverwood International
Smurfit – Stone Container Corporation
Weyerhaeuser Co.

The PCA HPV Task Force has filed multiple test plans covering various chemicals. Not all members of the Task Force produce the substances covered by this final submission.

I. Description of Rosins and Rosin Salts

The Pine Chemicals Association, Inc. (PCA) has sponsored six HPV chemicals known collectively as Rosins and Rosin Salts. The Test Plan for this group of substances was posted on EPA's HPV website on October 5, 2001, with comments from the EPA and the Physicians Committee for Responsible Medicine (PCRM), posted on March 11, 2002, and March 27, 2002, respectively. After reviewing these comments, PCA prepared a response which was subsequently posted on EPA's HPV website on June 21, 2002.

This group of chemicals consists of the following:

8050-09-7, Rosin
65997-06-0, Rosin, hydrogenated
68425-08-1, Rosin, distillation overheads
68783-82-4, Rosin, low boiling fraction
61790-50-9, Rosin, potassium salt
61790-51-0, Rosin, sodium salt

All of the members of this group are derived from rosin, which is a naturally occurring substance found in trees, predominantly pine trees. Rosin is composed primarily of resin acids, a class of tricyclic carboxylic acids, but also contains minor amounts of dimerized rosin and unsaponifiable matter. As complex mixtures, rosin and its derivatives are all considered as Class 2 substances.¹

Rosin is an important commercial material and has been used for centuries. Industrially, there are three different types of rosin: gum, wood and tall oil rosin, with the name indicating the way in which rosin is extracted from the tree. Gum rosin is obtained by slashing the tree and collecting the gummy exudates (oleoresin). This exudate consists of a mixture of rosin and turpentine and the rosin is recovered by distilling away the turpentine. Wood rosin is obtained by the solvent extraction of pine wood. Tall oil rosin is obtained by the distillation of tall oil, a by-product from the alkaline pulping of pine wood. In the United States, tall oil rosin is by far the most commercially important form of rosin.

The three rosins are chemically very similar. They all contain the same resin acids but the ratio of the acids is different. The difference arises because some of the resin acids are thermally unstable and isomerize to other resin acids during the production process. In 1991, the Pine Chemicals Association (then the Pulp Chemicals Association) proposed to the EPA that there should only be one CAS registry number to describe all

¹ As defined in the TSCA Inventory, "In terms of composition, some chemical substances are single compounds composed of molecules with particular atoms arranged in a definite known structure. For purposes of this discussion, such substances will be denoted Class 1 substances. Many commercial chemical substances are not in this class. They may have variable compositions or be composed of a complex combination of different molecules. These substances will be denoted Class 2 substances."

three types of rosin. In a letter dated March 13, 1992, the Inventory Section of the EPA agreed with this request stating, "... *rosin, CASRN 8050-09-7 will cover all types of rosin, irrespective of their method of production.*" Subsequently, the industry and the EPA have only used one CAS number for rosin. Thus, CAS# 8050-09-7 now also includes substances formerly reported as CAS# 8052-10-6.

A. Composition

Each species of pine tree has a somewhat different mix of resin acids. Even within a species, the mix of resin acids may be influenced by the climate and local terrain. However, all the members of this group are derived from rosin. Hydrogenated rosin, as the name implies, is made by the catalytic hydrogenation of rosin. Rosin, distillation overheads is formed as a by-product when rosin is processed at high temperatures and is made up primarily of resin acids and decarboxylated resin acids. While they have different CAS numbers, rosin, low boiling fraction, is essentially identical to rosin, distillation overheads. The sodium and potassium salts are simply rosin that has been reacted with the appropriate base. The general characteristics and composition of each of the substances in this category are addressed below.

1. Rosin (CAS# 8050-09-7)

Rosin is a pale yellow, glass-like solid. The description of rosin listed in Appendix A of the TSCA Inventory is "*A complex combination derived from wood, especially pine wood. Composed primarily of resin acids and modified resin acids such as dimers and decarboxylated resin acids. Includes rosin stabilized by catalytic disproportionation.*"

The composition of a typical tall oil rosin is shown in Table 4. As is evident, it consists of several major components and some minor ones. Rosin also contains trace quantities of numerous other components. Due to its complex composition, rosin is classified as a Class 2 substance. The structures of some of the more important resin acids found in rosin are shown in Figure 1.

Commercially, rosin is rarely categorized by its composition. Rather, it is usually specified by its softening point, acid value, and color (Zinkel and Russell 1989). In fact, the Naval Stores Act of 1923 (7 USC §§ 91-99), as amended in 1951, and regulations promulgated thereafter by USDA list only color as a specification for rosin.

Table 4

Composition of a Typical Tall Oil Rosin

Resin acid	Composition
Pimaric	4%
Sandarcopimaric	4%
Communic	1%
Palustric	8%
Isopimaric	11%
Abietic	38%
Dehydroabietic	18%
Neoabietic	3%
Other compounds ^a	12%

a: other resin acids, high boiling fatty acids and unsaponifiable matter.

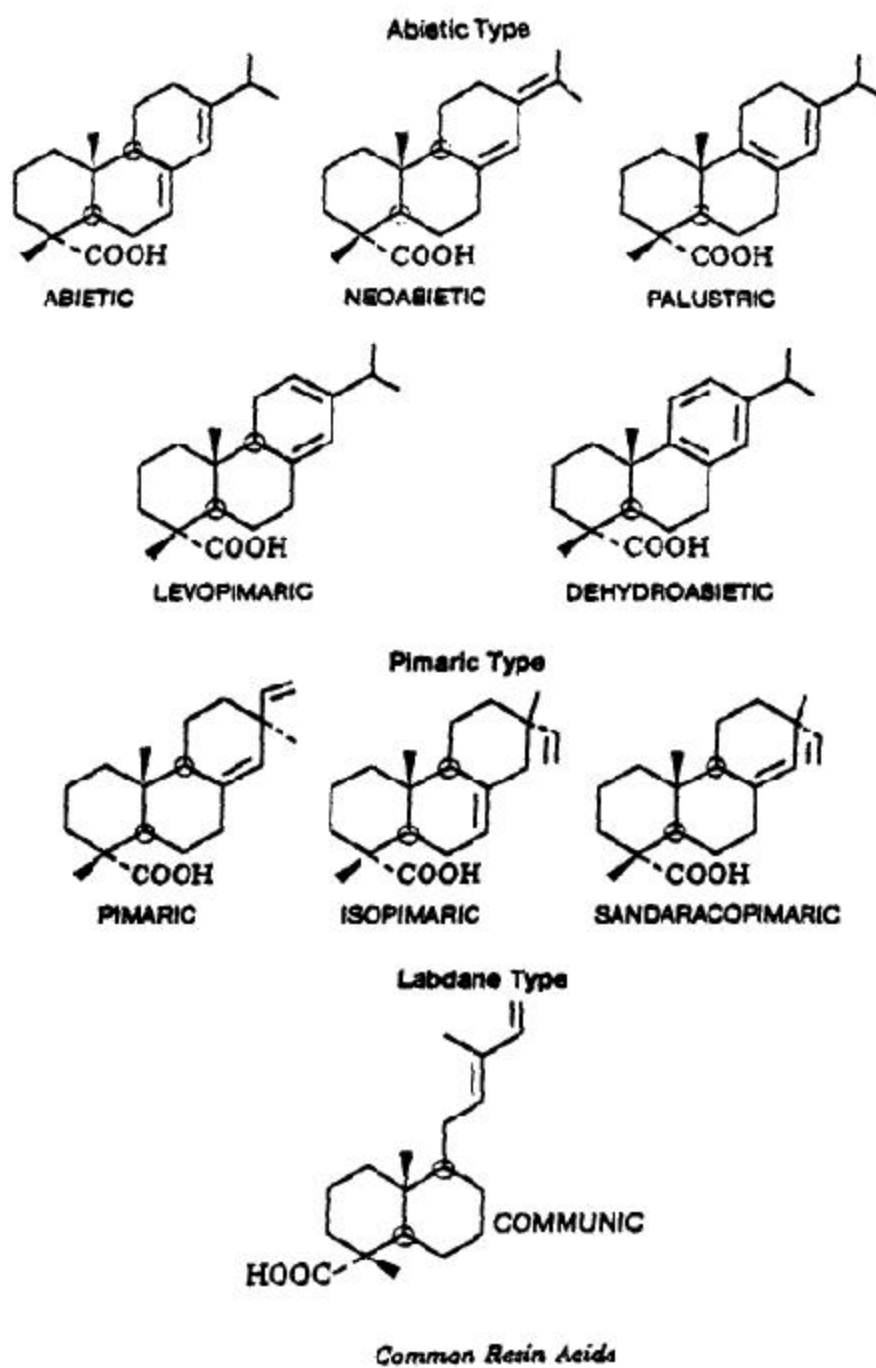


Figure 1. Representative resin acids found in rosin and its derivatives.

After reviewing the *Test Plan for Rosin and Rosin Salts*, EPA noted that PCA did not provide typical compositional ranges for the three types of rosin, all of which have the same CAS Number (i.e., 8050-09-7). Table 5 from the PCA publication "*Tall Oil and its Uses*" provides some typical values for the composition of the three different types of rosin: gum, wood and tall oil.

Table 5
Composition of Gum, Wood and Tall Oil Rosins

Components	Gum	Wood	Tall oil
Pimaric	2%	3%	3%
Palustric	18%	10%	10%
Isopimaric	18%	11%	7%
Abietic	20%	45%	35%
Dehydroabietic	4%	8%	20%
Neoabietic	18%	7%	4%

These values are just typical values and the actual composition will vary depending on the species of pine tree from which the rosin is obtained and the conditions under which it is processed. However, they illustrate that the general composition of the three types of rosin are similar.

2. Rosin, hydrogenated (CAS# 65997-06-0)

The composition of hydrogenated rosin is similar to rosin except that some of the double bonds in the resin acids have been removed. The conjugated double bonds in resin acids such as abietic acid are prone to oxidation and so catalytic hydrogenation is used to stabilize the molecule. The resulting product retains its color and other oxidation sensitive properties better than unmodified rosin. Like rosin, hydrogenated rosin is characterized primarily by its color, softening point stability and acid value rather than its chemical composition.

3. Rosin, Distillation Overheads (CAS# 68425-08-1) and Rosin, Low Boiling Fraction (CAS# 68783-82-4)

Rosin, distillation overheads, is one of several substances listed in the inventory that describe the product obtained when rosin is heated to the temperature at which it degrades. Another, virtually identical, substance is rosin, low boiling fraction. Descriptions of both these substances are listed in Appendix A of the TSCA Inventory and the descriptions of each are essentially the same. Rosin, distillation overheads, is described as *"the low boiling fraction obtained by the distillation of rosin. Contains decarboxylated rosin, decarboxylated resin acids, resin acids, terpenes and*

hydrocarbons derived from decarboxylated fatty acids." Rosin, low boiling fraction is described as *"A complex combination obtained by the distillation of rosin. This low boiling fraction consists primarily of decarboxylated rosin, resin acids, decarboxylated resin acids, terpenes and hydrocarbons derived from decarboxylated fatty acids."*

Therefore, for commercial purposes, as well as typical composition, these two substances are synonymous. Both of these low boiling rosin products are produced wherever rosin is processed at elevated temperatures but different companies give them different names. Thus, in reality, they are duplicate listings in the TSCA Inventory and not different substances. Because of this, testing for chemical/physical properties was only conducted on rosin, distillation overheads and no testing was done on the rosin, low boiling fraction. As these substances are by-products of other processes the composition can vary widely as shown in Table 6.

Table 6

**Composition of a Typical Rosin, Distillation Overheads or
Rosin, Low Boiling Fraction**

Fatty acids	1-5%
Rosin acids	30-60%
Hydrocarbons ^a	20-40%
Rosin aldehydes	10-20%
Rosin alcohols	5-10%
Rosin esters	1-10%

a: terpenic and from decarboxylated rosin acids and fatty acids

**4. Rosin, Potassium Salt (CAS# 61790-50-9) and Sodium Salt
(CAS# 61790-51-0)**

The rosin potassium and sodium salts are merely the simple alkali metal salts of unmodified rosin and are made by treating rosin with the appropriate base. As these substances are salts of a strong base and a weak acid they are alkaline with the pH depending on the concentration.

B. Commercial Uses of Rosins and Rosin Salts

Rosin is by far the most important member of this category from a commercial standpoint, with almost four times the volume of production as the other members of the group combined. The main use of rosin is in the production of derivatives or chemical intermediates that find a wide variety of industrial applications. The largest single application for rosin derivatives is in the production of printing inks, followed by adhesive, chewing gum, and coatings.

Salts of rosin are widely used in the paper and the soap and detergents industries. The sodium salts of rosin are used in paper sizing chemicals to give the finished product a better surface finish and water resistance. Potassium salts of rosin are used in the production of various soaps and detergents.

Rosin, hydrogenated is used in specialty adhesive applications where product stability and color are important. It is useful for these applications because it does not oxidize as readily as rosin.

Rosin, distillation overheads and rosin, low boiling fraction find application in the production of rosin derivatives for the end use applications described above, or if the quality of the substances is undesirable, they may be consumed for their fuel value.

C. Complexity of Analytical Methodology

All of the substances in this category are Class 2 substances. This, combined with the fact that rosin is essentially insoluble in water and decomposes on heating at high temperature, creates a variety of analytical challenges. Gas chromatography of methylated derivatives is the accepted method for the analysis of the members of this category. Because the solubility of rosin is very low (< 10 ppm) the reliability of the standard analytical method was verified at such low concentrations.

II. Rationale for Selection of Representative Compound for Testing

Rosin (CAS# 8050-09-7) was selected as the representative substance in this category for testing purposes because it is commercially the most important and the source of all of the other substances in this category. All the substances in this category are similar in chemical composition, being predominantly a mixture of resin acids or their salts. The selection of rosin as the substance to be tested is based on two factors. It has by far the greatest production volume; in the U.S. rosin production is almost four times higher than production of the other substances in this category combined. EPA guidance suggests that testing the substance produced at the greatest volume as the representative chemical of a category would be appropriate. Clearly, rosin fits this criterion.

Another criterion listed by EPA for grouping chemicals into a category is the use of the "family approach" of examining related chemicals when they are acids or acid salts. Although the salts of rosin have quite different physical characteristics, they are included in this category because they are quickly converted into the free acids when they are neutralized by acid or by dilution, as they would be under typical toxicity testing conditions. In summary, this group of chemicals fits the requirements of the EPA's HPV Challenge program for a chemical category, and rosin is the most appropriate representative test material from this category.

In reviewing the *Test Plan for Rosin and Rosin Salts*, EPA questioned whether rosin, distillation overheads and rosin, low boiling fraction belonged in the category and could be represented by rosin, the representative test substance. While agreeing that hydrogenated rosin, rosin potassium salt and rosin sodium salt “*are structurally similar or virtually identical to rosin*” -- the representative test substance, the Agency was concerned that with respect to toxicological or environmental properties, rosin might not represent rosin, distillation overheads and rosin, low boiling fraction due to their lower percentage of rosin acids and higher percentages of fatty acids, hydrocarbons and rosin aldehydes, alcohols and esters.

After carefully considering this issue, it was concluded that the rosin category would remain as originally proposed. However, an additional acute oral toxicity test (OECD 425, the up-down procedure) on rosin, distillation overheads (CAS # 68425-08-1) was conducted in order to demonstrate that test results on rosin can represent both rosin, distillation overheads and rosin, low boiling fraction. The determination of an LD₅₀ of >2000 mg/kg for rosin, distillation overheads, confirmed this decision.

III. Summary of Data

Rosin was tested for developmental toxicity and the three ecotoxicity endpoints. Rosin, distillation overheads was also tested for acute oral toxicity. Biodegradation was determined for all substances where data were lacking. In addition, the solubility and partition coefficients for all of the substances in this category were determined. Table 7 summarizes the results from all of the testing conducted on the substances in this category.

Table 7
Summary of Data
Rosin and Rosin Salts *

Chemical and CAS#	Required SID Endpoints										
	Partition Coef.	Water Sol. Mg/l	Biodeg. % @ 28 days	Acute Fish NOEL _r	Acute Daphnia NOEL _r	Acute Algae NOEL _r	Acute Oral LD ₅₀	Repeat Dose NOEL	Genetox (Bacteria)	Genetox (Mammalian cells)	Repro/ Develop. NOEL
Rosin 8050-09-7	1.9 - 7.7	0.9	32	1000 mg/l	750 mg/l	1000 mg/l	> 5000 mg/kg	105-200 mg/kg/day	No tumors in 2 yr. cancer bioassay ^a	No tumors in 2 yr. cancer bioassay ^a	275 mg/kg/day
Rosin, hydrogenated 65997-06-0	2.5 - 7.6	1.18	0.95	C	C	C	> 2000 mg/kg	200 mg/kg/day	No tumors in 2 yr. cancer bioassay ^a	No tumors in 2 yr. cancer bioassay ^a	C
Rosin, distillation overheads 68425-08-1	2.5 - 7.8	19.85	30	C	C	C	C	C	C	C	C
Rosin, low boiling fraction 68783-82-4	2.5 - 7.8	19.85	C	C	C	C	C	C	C	C	C
Rosin, potassium salt 61790-50-9	3.0 - 7.0	Miscible in H ₂ O	90	C	C	C	C	C	C	C	C
Rosin, sodium salt 61790-51-0	3.5 - 6.6	Miscible in H ₂ O	80	C	C	C	C	C	C	C	C

C= category read-down from data on rosin or rosin, hydrogenated; **a=** see text for explanation; ***No** testing was conducted for melting point, boiling point, vapor pressure, hydrolysis, photodegradation and transport and distribution between environmental compartments as explained in the text.

A. Physicochemical Data

The basic physicochemical data required in the SIDS battery includes melting point, boiling point, vapor pressure, partition coefficient (K_{ow}), and water solubility.

Class 2 substances are composed of a complex mixture of substances and are often difficult to characterize. Rosin and its derivatives are not only Class 2 substances, but also are derived from natural sources. Their composition is variable and cannot be represented by a single chemical structural diagram. Due to this “complex mixture” characteristic of rosin and related compounds, some physical property measurements, such as partition coefficient do not give single definitive results because the methodology used to determine these properties will actually fractionate or partition the substance into various components. Since the methodology will alter the actual sample composition, the results are likely to be erroneous, difficult to interpret, or meaningless.

In commenting on the *Test Plan for Rosins and Rosin Salts*, EPA while agreeing that these substances are not amenable to some physicochemical and environmental fate testing, suggested that data on water solubility and partition coefficients of the components abietic acid, dehydroabietic acid, isopimaric acid and their corresponding salts be submitted. However, PCA disagreed with this suggestion primarily because none of the individual components of these complex mixtures is representative of the mixture itself. Rather, this would provide information on chemicals that were outside of PCA’s commitment (i.e., substances with different CAS numbers).

1. Melting Point

Due to their complex nature, none of the members of this category have a well-defined melting point. These substances soften when heated and so have softening points rather than a true melting point. The softening point of these compounds can cover a wide range depending on the levels of resin acids, decarboxylated rosin and dimerized rosin in the sample, and hence these substances do not have specific softening points. The salts of rosin decompose on heating, and so melting point has no significance for these materials. Consequently, the melting point of these substances was not measured.

2. Boiling Point

All of the members of this category are produced by high temperature, high vacuum distillation and are non-volatile solids at ambient temperatures. A boiling point at ambient temperature has no significance because these materials will thermally decompose before they boil. Accordingly, measurement of this property was inappropriate for all the substances in this category.

3. Vapor Pressure

Vapor pressures for the rosins (which are solids) at ambient temperatures are effectively zero, and their experimental measurement is inappropriate. When rosin salts are dissolved in water, their solutions will reflect the vapor pressure of the water rather than the salt, and therefore measurement of this property is inappropriate.

4. Water Solubility

The water solubility of the compounds in this category was determined using OECD (105) and are shown below in Table 8.

Table 8

Chemical	Water Solubility (mg/l)
Rosin	0.9
Rosin, hydrogenated	1.18
Rosin, distillation overheads	19.85
Rosin, low boiling fraction ^a	19.85
Rosin, potassium salt	Miscible
Rosin, sodium salt	Miscible

a=because rosin, low boiling fraction is identical to rosin, distillation overheads, similar water solubility assumed.

All of these data are presented in detail in the Robust Summaries.

5. Partition Coefficient

The partition coefficients (i.e., K_{ow}) for five compounds in this category were determined. Although there were adequate data for rosin, it was retested with the other compounds in this category. Because all of these substances are Class 2 mixtures, the procedure (OECD 107) to determine the K_{ow} often yields a range of K_{ow} values rather than a single value representative of the mixture. Thus, the results reflect the partition coefficients of the components rather than the mixture. The partition coefficient data are shown below in Table 9.

Table 9

Chemical	Partition Coefficient (K_{ow})
Rosin	1.9 – 7.7
Rosin, hydrogenated	2.5 – 7.6
Rosin, distillation overheads	2.5 – 7.8
Rosin, low boiling fraction ^a	2.5 – 7.8
Rosin, potassium salt	3.0 – 7.0
Rosin, sodium salt	3.5 – 6.6

a=because rosin, low boiling fraction is identical to rosin, distillation overheads, similar partition coefficient assumed.

All of these data are presented in detail in the Robust Summaries.

B. Environmental Fate Data

The fate or behavior of a chemical in the environment is determined by the reaction rates or half-lives for the most important transformation (degradation) processes. The basic environmental fate data covered by the HPV Program include biodegradation, stability in water (hydrolysis as a function of pH), photodegradation and transport and distribution between environmental compartments (fugacity).

1. Biodegradation

Biodegradability provides a measure for the potential of compounds to be degraded by microorganisms. Depending on the nature of the test material, several standard test methods are available to assess potential biodegradability as reflected in the different tests shown in Table 10. For the substances in this category OECD method 302B was used for the salts and OECD method 301B was used for the non-salts. Two of the chemicals in this category (rosin and the sodium salt of rosin) had existing data on the biodegradation endpoint.

Table 10

Chemical	Percent Biodegradation At 28 Days	Test Method
Rosin	32	OECD 301D
Rosin, hydrogenated	0.95	OECD 301B
Rosin, distillation overheads	30	OECD 301B
Rosin, low boiling fraction ^a	30	
Rosin, potassium salt	89.5	OECD 302B
Rosin, sodium salt	80	OECD 307

a=because rosin, low boiling fraction is identical to rosin, distillation overheads, similar biodegradation assumed.

All of these data are presented in greater detail in the Robust Summaries.

2. Hydrolysis

Hydrolysis as a function of pH is used to assess the stability of a substance in water. Hydrolysis is a reaction in which a water molecule (or hydroxide ion) substitutes for another atom or group of atoms present in an organic molecule. If there is no functional group suitable to be displaced, then the organic compound is considered to be resistant to hydrolysis. None of the substances in the rosin category contains an organic functional group that might be susceptible to this physical degradative mechanism. Therefore, hydrolysis was not measured for any of the substances in this category.

In addition, low water solubility often limits the ability to determine hydrolysis as a function of pH. All of the non-salt rosin compounds have very low solubility in water. Therefore, these materials are expected to be stable in water and it would be unnecessary to attempt to measure the products of hydrolysis. With respect to the rosin salts, in an aqueous medium they hydrolyze (ionize) immediately, but form stable species. Consequently, it was also be unnecessary to measure this endpoint for the rosin salts.

3. Photodegradation

Due to their low water solubility and lack of any vapor pressure under ambient conditions, there is essentially no opportunity for any of these chemicals to enter the atmosphere. Thus, photodegradation is irrelevant. In addition, based on the constituents in these complex mixtures, there is no reason to suspect that they would be subject to breakdown by a photodegradative mechanism. Consequently, this endpoint was not determined for any of the substances in this category.

4. Transport and Distribution between Environmental Compartments

The transport and distribution between environmental compartments (i.e., fugacity) is intended to determine the ability of a chemical to move or partition in the environment. There are various mathematical models for estimating fugacity. One of the most frequently referenced models is the level III model from the Canadian Environment Modeling Centre at Trent University. Even the simplest of these models requires estimates of solubility, vapor pressure and octanol/water partition coefficient to estimate fugacity for a single component. For complex class 2 substances such as rosins and rosin salts, estimates of any one of these physical parameters for the various known components could span a range of more than an order of magnitude. When combining three or more parameters of equally variable ranges to derive estimates for different environmental media, the variability in the estimate for any given medium could grow geometrically to three or more orders of magnitude. This suggests that any estimates based on arbitrarily selected individual components would be essentially useless for any practical purpose. Add to this the additional fact that there is variability in the chemical composition of these substances (as illustrated in Table 5 and 6 above) and the possible permutations become unmanageable. Consequently, for complex mixtures such as rosin and rosin salts, the mathematical models which rely upon estimates for individual components are of no practical use in predicting environmental fate. Therefore, due to the inability to provide usable inputs to the required model, no determination of transportation and distribution between environmental compartments was undertaken for rosin and rosin salts.

C. Ecotoxicity Data

The basic ecotoxicity data that are part of the HPV Program include acute toxicity to fish, daphnia and algae. While there were existing data on these endpoints for some of the substances in this grouping category, these data are conflicting and it was impossible to determine which, if any, of these findings is representative of true ecotoxicity. The inconsistencies in how water samples were prepared for testing these endpoints render these data inadequate. Consequently, acute toxicity to fish, daphnia and alga was retested for rosin under conditions that maximize the solubility under the specific test exposure conditions, but reduce exposure to insoluble fractions, which may cause nonspecific toxicological effects. In addition, the effect of both filtering, to further minimize nonspecific physical effects, and of reducing the pH to the lower end of the acceptable range for test organism survival, was also investigated for changes in toxicological effects. The results of preliminary tests were used to select the most appropriate test conditions for the definitive test for each species.

In reviewing the *Test Plan for Rosin and Rosin Salts*, EPA noted that there were two fish acute 96-hour toxicity studies on abietic and dehydroabietic acids. However, it is the position of PCA that its commitment to the HPV program pertains to testing rosin as a complex mixture and not to any individual

components of this mixture. Consequently, these data were not considered in the evaluation of the potential ecotoxicity of rosin. It should be noted, however, that the lack of acute toxicity to fish of rosin at the empirically determined limit of water solubility suggests that no individual components of this mixture are toxic to fish.

Also in its comments on the *Test Plan for Tall Oil and Related Substances*, EPA suggested that PCA consider a 21-day chronic daphnid reproduction test using a flow-through method with measured concentrations. After considering this suggestion, it was determined not to undertake a 21-day chronic daphnid reproduction test. The methodology for preparing the water for the ecotoxicity testing of rosin was identical to that used to determine the solubility of this substance. This procedure was adopted in order to ensure that ecotoxicity testing was conducted at the limit of actual water solubility. Given the extremely low solubility of the material, the recommendation for a 21-day test using a flow-through method would be impractical due to the amount of water that would be required and the difficulty in performing the necessary serial analytical measurements.

The ecotoxicity data are summarized in Table 11 below and demonstrate that rosin is non-toxic to fish, daphnia and algae.

Table 11

Chemical	Fish 96 hr. *NOEL_r	Daphnia 48 hr. NOEL_r	Algae 72 hr. NOEL_r
Rosin	1000 mg/l	750 mg/l	1000 mg/l

*NOEL_r = No Observed Effect Loading Rate

These data are presented in greater detail in the Robust Summaries.

D. Human Health Effects Data

1. Acute Oral Toxicity

Acute oral toxicity studies investigate the effect(s) of a single exposure to a relatively high dose of a substance. This test is conducted by administering the test material to animals (typically rats or mice) in a single gavage dose. Harmonized EPA testing guidelines (August 1998) set the limit dose for acute oral toxicity studies at 2000 mg/kg body weight. If less than 50 percent mortality is observed at the limit dose, no further testing is needed. A test substance that shows no effects at the limit dose is considered essentially nontoxic. If compound-related mortality is observed, then further testing may be necessary.

Summary of Acute Oral Toxicity Data

Both rosin and hydrogenated rosin are non-toxic following acute oral exposure. The acute oral LD₅₀ values of various rosins (wood, gum and tall oil) are > 4000 mg/kg in rats, mice and guinea pigs. The acute oral LD₅₀ value of hydrogenated rosin is > 32,000 mg/kg. These data are presented in greater detail in the Robust Summaries.

In their comments on the *Test Plan for Rosins and Rosin Salts*, EPA was concerned that the results from toxicity testing of rosin might not represent rosin, distillation overheads and rosin, low boiling fraction. In response to this concern, an additional acute toxicity test (OECD 425, up-down procedure) was conducted on rosin, distillation overheads. The LD₅₀ of >2000 mg/kg for rosin, distillation overheads confirms that this compound shares a similar lack of toxicity as the other substances in this category.

2. Repeat Dose Toxicity

Subchronic repeat dose toxicity studies are designed to evaluate the effect of repeated exposure to a chemical over a significant period of the life span of an animal. Typically, the exposure regimen in a subchronic study involves daily exposure (at least 5 consecutive days per week) for a period of not less than 28 days or up to 90 days (i.e., 4 to 13 weeks). The HPV program calls for a repeat dose test of at least 28 days. The dose levels evaluated are lower than the relatively high doses used in acute toxicity (i.e., LD₅₀) studies. In general, repeat dose studies are designed to assess systemic toxicity, but the study protocol can be modified to incorporate evaluation of potential adverse reproductive and/or developmental effects.

Summary of Repeat Dose Toxicity Data

The data demonstrate low toxicity for both rosin and hydrogenated rosin in repeat dose tests. Rosin was tested in a 90-day subchronic toxicity study in rats. The test material was administered to Sprague-Dawley rats in the diet at concentrations of 0, 0.01, 0.05, 0.20, 1.0 and 5.0% for 90 days. The approximate doses were 0, 10, 50, 200, 1000, or 5000 mg/kg/day. Parameters evaluated included clinical signs, mortality, body weight, body weight gain, food consumption, hematology, clinical chemistry, urinalysis, gross and microscopic pathology, and organ weights.

All animals in the 5% dose group died within a week due to palatability issues resulting in complete cessation of food consumption. Some animals in the 1% dose group also failed to gain weight compared to controls due to decreased food consumption that resulted in some decreased organ weight to body weight ratios. No changes in hematology, clinical chemistry or urinalysis parameters were

measured at any dose level. At gross pathology, no treatment-related effects were noted. No consistent organ weight changes and no histopathological effects were reported. Based on these data, the No Observed Effect Level (NOEL) was 0.20% (200 mg/kg/day). These data are presented in greater detail in the Robust Summaries.

Other 90-day subchronic studies confirm the low toxicity of rosin. In these studies, the only effect noted was either death due to palatability resulting in non-consumption of food or depression of body weight gain at the highest doses tested. In a dietary study with hydrogenated rosin, weanling Sprague-Dawley rats were exposed at concentrations of 0, 0.01, 0.05, 0.2, 1, or 5% for 90 days. The approximate doses were 0, 10, 50, 200, 1000, or 5000 mg/kg/day. Parameters evaluated included clinical signs, mortality, body weight, body weight gain, food utilization, hematology parameters, urinalysis, organ weights and gross and microscopic pathology.

All the animals in the high-dose group died prior to study termination due to treatment-related starvation through food refusal. In the 1% group, body weight was significantly decreased in both males and females, and food consumption was decreased. Food utilization was not affected at a dietary concentration of 1% indicating that the reduced food consumption was related to palatability. No treatment-related effects on hematology, urinalysis, or gross or microscopic pathology. Based on these data, the NOEL was 0.2% (200 mg/kg/day). These data are presented in greater detail in the Robust Summaries.

3. Genotoxicity – In vitro

Genetic testing is conducted to determine the effects of substances on genetic material (i.e., DNA and chromosomes). The gene, which is composed of DNA, is the simplest functional genetic unit. Mutations of genes can occur spontaneously or as a consequence of exposure to chemicals or radiation. Genetic mutations are commonly measured in bacterial and mammalian cells, and the HPV program calls for completing both types of tests.

Summary of Genotoxicity Data

Rosin and hydrogenated rosin have been tested for potential carcinogenicity in several two-year bioassays conducted in rats. None of these studies demonstrated any evidence of carcinogenicity. The primary effect was depressed weight gain at the highest dose, confirming that a maximally tolerated dose was achieved. Since the primary purpose of *in vitro* bacterial and mammalian genotoxicity tests is to determine if a chemical might have the potential to be a direct-acting DNA reactive carcinogen, the negative carcinogenicity studies eliminate the need to test for potential genotoxicity.

In reviewing the *Test Plan for Rosin*, EPA disagreed with PCA's reliance on several negative 2-year carcinogenicity studies on rosin to fulfill the genotoxicity endpoint. More specifically, EPA's comments disagreed with the statement from the rosin test plan that *"Since the purpose of in vitro bacterial and mammalian mutagenicity tests is to determine if a chemical might have the potential to be a direct-acting DNA reactive carcinogen, the negative carcinogenicity studies eliminate the need to test for potential genotoxicity."* The comments then go on to list a number of genetic diseases and conditions (e.g., Down's syndrome, cystic fibrosis, hemophilia, sickle-cell anemia, allergies, mental retardation, etc.) with the implication that genotoxicity testing is also able to predict the ability of a chemical to cause these adverse outcomes. However, there is no evidence that the two genotoxicity screening tests that comprise the SIDS battery of tests (i.e., bacterial mutation and chromosomal aberration) have this ability. The likelihood that such testing would predict the non-cancer endpoints noted in EPA's comments is also tempered by the observation in Casarett & Doull's textbook on Toxicology (1996), *"No clear evidence exists for the induction of heritable alterations by radiation or chemicals in human germ cells."*

In addition, in the early stages of the HPV program, there was uncertainty about the format in which robust summary data would be submitted to EPA. In a meeting with Dr. Oscar Hernandez to discuss this issue, the summarized rosin data were used to illustrate a possible robust summary format. The above statement concerning the use of negative carcinogenicity data to eliminate the need to test for potential genotoxicity was included in the summarized data as part of this discussion. While Dr. Hernandez indicated that mutagenicity testing might indicate the potential for possible endpoints other than cancer, he readily agreed that for purposes of the HPV program, a negative cancer bioassay was a suitable surrogate for genotoxicity testing. Accordingly, bacterial gene mutation and chromosomal aberration testing on rosin was not undertaken.

4. Reproductive and Developmental Toxicity

Reproductive toxicity includes any adverse effect on fertility and reproduction, including effects on gonadal function, mating behavior, conception, and parturition. Developmental toxicity is any adverse effect induced during the period of fetal development, including structural abnormalities, altered growth and post-partum development of the offspring.

The "toxicity to reproduction" aspect of the HPV Challenge Program can be met by conducting a reproductive/developmental toxicity screening test or adding a reproductive/developmental toxicity screening test to the repeat dose study (OECD 421 or OECD 422, respectively).

Summary of Reproductive/Developmental Toxicity Data

As noted in the SIDS guidelines for the reproduction toxicity endpoint, *"when a 90-day repeated dose study is available and demonstrates no effects on the reproductive organs, in particular the testes, then a developmental study can be considered as an adequate test to complete information on reproduction/developmental effect."* Rosin and hydrogenated rosin have been tested in 90-day repeat dose studies as well as in two-year bioassays. Both types of studies included histopathology of reproductive organs (*i.e.*, testes, ovaries, uterus) and showed no evidence of reproductive organ toxicity at any dose level. Therefore, these studies satisfy the SIDS reproductive toxicity endpoint. However, since neither of these studies evaluated the developmental toxicity endpoint, this was determined on rosin using OECD protocol 421.

Rosin was administered via the diet to four groups of 10 male and 10 female Sprague-Dawley rats at concentrations of 0, 1000, 3000 and 10000 ppm. The males were dosed for at least 4 weeks, starting from 2 weeks prior to mating while the females were dosed from 2 weeks prior to mating until at least Day 4 of lactation. All animals were monitored for clinical signs, body weight, food consumption, mating and litter performance. At termination, the adults received a gross necropsy, with weights of testes and epididymides recorded; histological examination was restricted to the testes, epididymides and ovaries from the control and high dose animals.

Rosin at 10000 ppm was associated with reduced weight gain/ weight loss and reduced food consumption for the first few weeks of treatment. The deficits in body weight were never regained. Food consumption was reduced throughout gestation and body weight gain was reduced during the first half of gestation.

At 10000 ppm the mean number of implant sites per pregnancy was slightly decreased resulting in a subsequent reduction in litter size. Mean litter and pup weights were also slightly reduced. However, none of these effects were significantly different from controls. The effects on implantation, litter size and fetal weight were likely secondary to the effects on food intake and subsequent weight gain in the adult females. Litter survival, as indicated by the birth index and viability index, was similar in all groups. There were no effects of treatment on mating performance, fertility or the duration of gestation. No obvious external abnormalities were noted in the pups at any dose level. Testes and epididymides weight were essentially similar in all groups and there were no histology findings that could be attributed to treatment with rosin.

Body weight gain was slightly reduced in males at 3000 ppm although this was not significantly different from controls. The minor change in food consumption was too small to be attributed to treatment.

The no observed effect level (NOEL) for adults was 1000 ppm (93 mg/kg/day) (due to slight weight changes at 3000 ppm) and the NOEL for reproductive/developmental effects was 3000 ppm (275 mg/kg). These data are presented in greater detail in the Robust Summaries.

IV. Category Justification: Validation of Rosin as Representative of Other Category Members for SIDS Endpoints

All the substances in this category are similar in chemical composition, being predominantly a mixture of resin acids or their salts. In addition, rosin is the raw material from which all the other category members are derived. Although the salts of rosin have quite different physical characteristics, they are included in this category because they are quickly converted into the free acids when they are neutralized by acid or by dilution, as they would be under typical toxicity testing conditions. With respect to rosin, distillation overheads and rosin, low boiling fraction they are essentially identical substances with both products being produced wherever rosin is processed at elevated temperatures. In comparison with rosin, both contain a lower percentage of rosin acids and higher percentages of fatty acids, hydrocarbons and rosin aldehydes, alcohols and esters. Because of this, an additional acute oral toxicity test on rosin, distillation overheads was conducted in order to demonstrate that test results on rosin can represent both rosin, distillation overheads and rosin, low boiling fraction. The determination of an LD₅₀ of >2000 mg/kg for rosin, distillation overheads, confirmed this.

In addition, it should be noted that the totality of data for the category of rosin esters (described in the Final Submission for Rosin Esters) also demonstrates that none of the chemicals in this category are toxic. In summary, based on adequate toxicity data and a detailed understanding of the composition of the six substances in this category, the data on rosin (augmented by data on rosin, distillation overheads) can be reliably extrapolated to the entire category thereby validating the composition of the category.

V. Hazard Characterization of Rosins and Rosin Salts

For potential human health effects, the totality of the SIDS data demonstrates that rosin is non-toxic. Because all of the chemicals in this group are derived from or closely related to rosin, as well as the fact that all members of this group are qualitatively similar in chemical composition, based on the category approach, it can be inferred that all of the substances in this group are also non-toxic.

Rosin has no acute oral toxicity (i.e., LD₅₀ > 2,000 mg/kg), and repeat dose toxicity data demonstrate no observed effect levels (NOEL) of approximately 105 - 200 mg/kg/day. These were based on body/organ weight effects due to decreased

food consumption. No histopathological changes were observed in any organ; reproductive organs (*i.e.*, testes, ovaries, uterus) showed no evidence of toxicity at any dose level.

There was no evidence of reproductive or developmental toxicity in the screening test (OECD 421) with a NOEL of approximately 275 mg/kg/day; the only finding of note was a decrease in implantation sites and subsequent reduction in litter size at a dose of approximately 825 mg/kg/day, which was likely due to reduced food intake and body weight deficits. The lack of acute oral toxicity (*i.e.*, $LD_{50} > 30,000$ mg/kg) for rosin, hydrogenated and rosin, distillation overheads (*i.e.*, $LD_{50} > 2000$ mg/kg) is confirmatory of the lack of acute toxicity of the substances in this category. The lack of carcinogenic effects in chronic feeding studies on rosin and rosin, hydrogenated suggest that neither of these compounds have the ability to cause mutations. Consequently, no adverse health consequences would be associated with any anticipated exposures to rosin or rosin salts.

With respect to potential ecotoxicological effects, the totality of SIDS data on rosin, the representative substance in this category, demonstrate that the substances in this category are non-toxic to aquatic organisms including fish, daphnia and algae. The No Observed Effect Loading Rate (NOEL_r) for rosin on fish and alga was 1000 mg/l while the NOEL_r for effects in daphnia was 750 mg/l.

VI. Potential Exposure to Rosin and Rosin Salts

This brief summary provides an overview of market end uses and potential exposure to products derived from tall oil, a major feed stock to the pine chemicals industry with emphasis on rosins and rosin salts. This information along with hazard data developed as part of the High Production Volume Chemical Testing Program is useful in evaluating the potential risks (if any) that might be associated with various uses of rosin and rosin salts.

Two primary fractions (rosin and fatty acids) are derived from the initial processing of tall oil. Tall oil rosin is consumed almost entirely in the production of other chemical intermediates. Rosin is reacted in a variety of ways to form salts, adducts, esters, dimers and other reaction products which find application in the production of printing inks, adhesives (primarily hot melt packaging adhesives), paper size, and coatings. These uses would be considered non-dispersive in that the rosin derived chemical is reacted or otherwise contained within the article in which it is being used. It is estimated that greater than 80% of the various rosin derivatives are used in the above type of applications where potential exposure is limited to contact with the article in which the rosin product is contained. As a result, inhalation exposure or volatilization to air is minimal. Exposure in the listed applications is generally limited to dermal contact during the processing, finishing and shipping of the products of which they become a part. Approximately 3% of rosin is reacted to form specific rosin esters which are marketed in to the chewing

gum industry. These derivatives are approved for direct food contact by the US FDA

Human exposure is limited by the fact that virtually all rosins and rosin salts are industrial intermediates consumed in the production of other chemicals. Consequently, there is little, if any, potential for exposure of the general consumer population. Environmental exposure is limited by the fact that the chemical processes used in the tall oil industry are essentially closed system processes where temperature and pressure are carefully controlled.

Environmental releases from tall oil processing plants are limited to (1) treated waste water discharge, and (2) ambient emissions following treatment with scrubbers or thermal oxidizers. Waste water can be generated from operation of the plant pressure control system or from minor spills and leaks associated with the process and/or handling of chemical products and routine housekeeping activities. In all cases the waste water is collected, the stream is treated to remove any free oil, and is then discharged into a larger biological waste treatment facility (either municipal treatment system or the treatment system of the paper mill). Any air emissions generated from the pressure control system or from the storage and transfer of various streams, are generally collected and treated in chemical scrubbers or thermal oxidizers.

The entire array of tall oil based chemicals and their related processing steps are best depicted by a “family tree” or flow diagram rather than a listing of discrete independent chemicals. Such a diagram demonstrates how various “parent” chemicals are consumed in the production of down stream chemicals. Consequently, it is inappropriate to sum production volumes. Figure 2 is a representation of the “family tree” for tall oil products and illustrates the relationship between these products. Based on industry data, approximately 95% of rosin is consumed during the production of other downstream products.

Table 12 illustrates general use categories and potential exposures to rosin and rosin salts. Of the various rosins, it is estimated that greater than 95% are consumed as intermediates in the production of the wide array of products derived from rosin. Potential exposure in all of these industrial applications would be limited to dermal contact during manufacture of the numerous products derived from rosin. The only other potential exposure to any of the substances in this category occurs during their production from activities such as changing reaction vessels, sampling for quality control, transferring material from one work area to another, loading and unloading bulk containers, changing filters, and cleaning equipment. The lack of water solubility of these compounds demonstrates that they are not bioavailable to aquatic organisms; this is confirmed by the lack of ecotoxicity to daphnia, fish and algae.

Figure 2
U.S. TALL OIL INDUSTRY

PRODUCTION & MARKET DISTRIBUTION
POUNDS/YEAR (000)

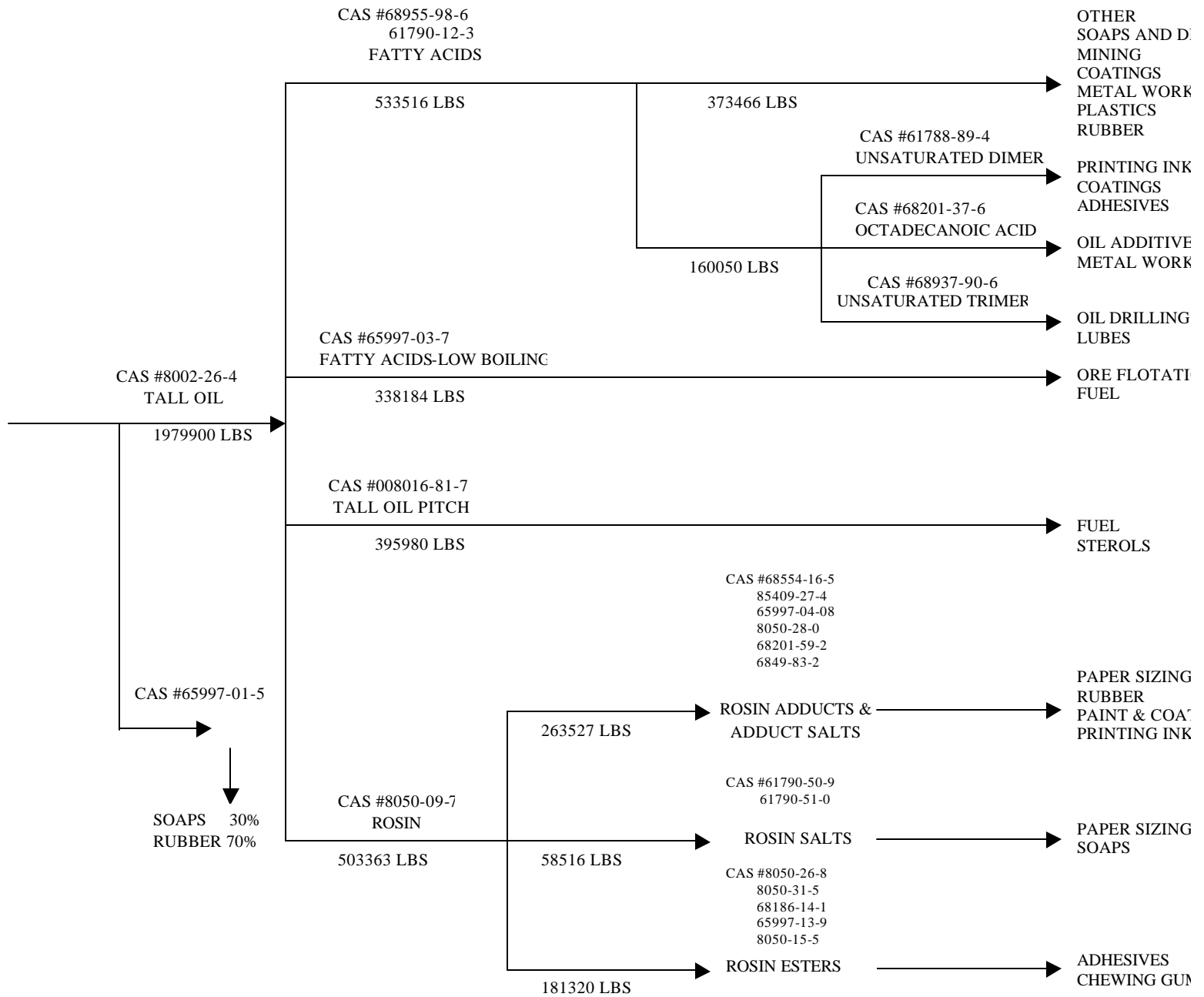


Table 12

Distribution, Application and Potential Occupational Exposure to Rosins and Rosin Salts

Substance	CAS #	Primary Function	Use Category	Major End Use Application	%
Rosin	8050-09-7	Chemical intermediate	Site limited	Derivative production	95
Rosin, hydrogenated	65997-06-0	Chemical intermediate	Site limited	Derivative production	95
Rosin, distillation overheads	68425-08-1	Chemical intermediate	Site limited	Derivative production Fuel	95 5
Rosin, low boiling fraction	68783-82-4	Chemical intermediate	Site limited	Derivative production Fuel	95 5
Rosin, potassium salt	61790-50-9	Chemical intermediate	Site limited	Paper sizing Soaps	95 5
Rosin, sodium salt	61790-51-0	Chemical intermediate	Site limited	Paper sizing Soaps	95 5

References

Casarett & Doull's Toxicology; The Basic Science of Poisons. 1996. C. Klaassen, Ed. 5th Ed. McGraw-Hill, New York.

EPA. 2000. Data Collection and Development on High Production Volume (HPV) Chemicals. Fed. Reg. Dec. 26, Vol. 65(248): pp. 81686-81698.

Zinkel, D.F. and Russell, J., Eds. 1989. Naval Stores. Production, Chemistry, Utilization. Pulp Chemicals Association, New York.

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